

Remarks.

Support for the Amendments

The foregoing amendment to the specification is sought to correct an inadvertent typographical error. Therefore, this amendment does not add new matter.

Support for new claim 69 can be found throughout the specification, particularly at page 10, lines 12-16; throughout pages 31-33; and throughout the Examples. Therefore, these amendments do not add new matter, and their entry and consideration are respectfully requested.

Status of the Claims

By the foregoing amendments, claim 69 is sought to be added. Upon entry of the foregoing amendments, claims 52-69 are pending in the application, with claims 52 and 69 being the independent claims.

Summary of the Office Action

In the Office Action dated March 25, 2004, the Examiner has made two rejections of the claims. Based on the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding rejections and that they be withdrawn.

The Rejection Under 35 U.S.C. § 112, Second Paragraph

In the Office Action at pages 2-3, the Examiner has rejected claims 52-68 under 35 U.S.C. § 112, second paragraph, alleging that the term "portions thereof" as it relates to recombination sites is unclear. Applicants respectfully traverse this rejection.

The Examiner's attention is drawn to the present specification at page 28, lines 5-19, where the phrase "portions of recombination sites" is defined. "Portions of recombination sites comprise at least 2 bases, at least 5 bases, at least 10 bases or at least 20 bases of the recombination sites of interest." Specification at page 9, lines 7-9. Based on this definition, Applicants respectfully submit that the ordinarily skilled artisan would readily understand the term "portions thereof" as it is used in the present claims with respect to recombination sites. Applicants therefore respectfully submit that the present claims clearly point out and distinctly claim the subject matter of the present invention.

In view of the foregoing remarks, Applicants respectfully request that the rejection of claims 52-68 under 35 U.S.C. § 112, second paragraph, be reconsidered and withdrawn.

The Rejection Under 35 U.S.C. § 102(b) Over Bebee

In the Office Action at pages 3-4, the Examiner has rejected claims 52-53, 55, 57-61 and 66-67 under 35 U.S.C. § 102 (b), as being anticipated by Bebee *et al.*, U.S. Patent No. 5,434,066 (hereinafter "Bebee"). Applicants respectfully traverse this rejection.

The Examiner states that Bebee discloses the generation of different vectors where desired sequences were obtained from the phage P1 genome via PCR amplification and therefore concludes that Bebee discloses the presently claimed invention. Applicants respectfully disagree with this conclusion.

Present claim 52 (and hence claims 53, 55, 57-61 and 66-67 that depend ultimately therefrom and that are also rejected over Bebee) recites an *in vitro* method for synthesizing one or more nucleic acid molecules comprising one or more recombination sites, the method

comprising: obtaining at least one isolated linear nucleic acid molecule; contacting the molecule *in vitro* with one or more adapters which comprise at least a first recombination site or portions thereof under conditions sufficient to add one or more of the adapters to one or more termini of the linear nucleic acid molecule; and mixing the linear nucleic acid molecule with at least one vector *in vitro* in the presence of at least one recombination protein, under conditions sufficient to cause recombination of the linear nucleic acid molecule with the vector.

Applicants respectfully submit that Bebee does not disclose every element of claim 52 (and hence the dependent claims noted above), and therefore cannot anticipate the claimed invention. Under 35 U.S.C. § 102, a claim can only be anticipated if every element in the claim is expressly or inherently disclosed in a single prior art reference. *See Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 771 (Fed. Cir. 1983), *cert. denied*, 465 U.S. 1026 (1984).

As discussed in the previous reply, dated January 5, 2004 (incorporated by reference herein in its entirety), Applicants submit that Bebee does not disclose the *in vitro* methods of the presently claimed invention, being limited instead to *in vivo* recombination wherein the recombination takes place inside of host cells (*see, e.g.*, Bebee in the title; in the abstract; at column 2, lines 47-55; at column 3, lines 46-58; in Example 2, at column 12, lines 16-20; and in Example 5, at columns 17-20). The Examiner's attention is specifically drawn to Bebee at column 12, lines 58-60, which discloses the use of *in vivo* recombination to generate the pZL plasmid. While Bebee discloses the treatment of the resultant plasmid with the Cre recombination protein *in vitro*, it is not until this plasmid is "transformed into *E. coli*

cells" (emphasis added) that the recombination reaction occurs and the pZL plasmid is generated. Applicants respectfully submit that Bebee does not disclose *in vitro* recombination between a linear nucleic acid molecule *and a vector* as recited in present claim 52, and therefore does not disclose every element of the present claims.

Hence, in view of *Kalman*, Bebee cannot and does not anticipate the presently claimed invention. Reconsideration and withdrawal of the rejection of claims 52-53, 55, 57-61 and 66-67 under 35 U.S.C. § 102(e) over Bebee are respectfully requested.

Conclusion

All of the stated grounds of rejection have been properly traversed. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn, and that all pending claims be allowed.

Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in black ink, appearing to read "B. J. Del Buono", with a large, stylized flourish at the end.

Brian J. Del Buono
Attorney for Applicants
Registration No. 42,473

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1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600

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